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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

HENDRICKS, KEITH D

ART UNIT

PAPER NUMBER

1761

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/909,464             | LANAHAN ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Keith Hendricks        | 1761                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 26 December 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1,4-43,51,53-56 and 58 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,4-43,51,53-56 and 58 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION*****Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, 8-15, 19-23, 26-35, 39-43, 51 and 53-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Further, the specification, while being enabling for the use of the alpha-galactosidase and its encoding nucleotide structure from *Thermotoga maritima*, does not reasonably provide enablement for the use of an alpha-galactosidase or its encoding nucleotide structure from either of *Thermotoga elfii* or *Thermotoga* sp. T2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants' arguments filed December 26, 2002, have been fully considered but they are not persuasive. At page 5 of the response, applicants state that "the Examiner has provided no objective evidence to doubt the veracity of Applicants' specification, or that the invention does not work as described." Applicants go on to say that "one skilled in the art would be able to isolate alpha-galactosidase or produce a recombinant enzyme from *T. elfii* and *T. sp. T2* without undue burden using no more than routine skill." This is not deemed persuasive for the reasons of record.

The Examiner has, in fact, provided sufficient evidence to place the availability and enablement of *T. elfii* and *T. sp. T2* alpha-galactosidase in doubt. See again pages 2-3 of the previous Office action, specifically detailing the situation and facts. Therein, it was stated that

The alpha-galactosidase from *Thermotoga* sp. T2 is not specifically disclosed as available in the instant specification, and thus provides no guidance as to where and how one skilled in the art would obtain and use this enzyme. It appears that the T2 enzyme was, at least, known in the art (for example, see Y. Koyama et al., *Applied and Environmental Microbiology*, 1990, vol 56: 2251-2254). However, this reference states that the "**expression of the introduced alpha-galactosidase gene was not ascertained**" (pg. 2253), and there is no disclosure of the isolation of the actual enzyme from *Thermotoga* sp. T2. Thus, the examiner is not aware of the public availability of the alpha-galactosidase from either *Thermotoga* sp. T2, or *Thermotoga elfii*. If applicants possess such knowledge, they are requested to present it in the subsequent response to this Office action.

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Thus, the Examiner has provided factual evidence to support the position of the Office.

Applicants' statement that "one skilled in the art would be able to isolate alpha-galactosidase or produce a recombinant enzyme from *T. elfii* and *T. sp. T2* without undue burden using no more than routine skill", flies in the face of this evidence, and is not well taken. The burden has shifted to applicants to provide sufficient evidence that one skilled in the art was able to practice the invention as of the filing date of the instant application. Applicant may not overcome this rejection by simply stating that "one skilled in the art would be able to isolate" the enzyme from sources, where prior attempts in the art have failed. The Office lacks further "evidence" of the lack of enablement, solely because of the lack of evidence to support applicants' claims. In other words, if the enzymes were not isolated and available to one skilled in the art at the time the invention was made, then no prior art 'evidence' would be available to the Office.

Again, as previously stated, while it is theoretically possible, and perhaps even plausible, that one skilled in the art would be able to eventually obtain the enzyme from *Thermotoga* sp. T2, or even *Thermotoga elfii*, plus further isolate the enzyme, form DNA probes for its successful expression, and subsequently use these items in the methods and products of the instant claims, this would be far removed from the teachings and enablement of the instant specification. Again, the specification does not place one skilled in the art in possession of these materials, and does not provide a sound, repeatable means by which one skilled in the art would be able to arrive at these claimed features. Thus, simply because applicants have provided the names of two other known *Thermotoga* species, from which alpha-galactosidases *could* be isolated and utilized, does not render the use of such enzymes, as enabled.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-8, 11-13, 15-18 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Liebl et al. (of record). The reference and rejection are incorporated as cited in a previous Office action.

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Applicants' arguments filed December 26, 2002, have been fully considered but they are not persuasive. At page 7 of the response, applicants state that the independent claims have been amended to recite that the substrate is "intended for use as an animal feed or human food."

This is not deemed persuasive for the reasons of record. In response to applicants' argument, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, applicants' claims broadly refer to a "galactose-containing oligosaccharide present in a substrate", which is "intended for use as an animal feed or human food". However, the substrate of the reference meets the physical, tangible properties of the claimed invention, regardless of the eventual use, and thus the claims are anticipated by the reference.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-43, 51, 53-56 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yernool et al. (US PAT 6,150,171), in view of the combination of Liebl et al., and Bylina et al. (WO 98/24799). The reference and rejection are incorporated as cited in a previous Office action.

Applicants' arguments filed December 26, 2002, have been fully considered but they are not persuasive. At page 8 of the response, citing known case law, applicants state that "both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure." Further, applicants state at page 9 of the response, that there is no teaching, motivation or suggestion in Yernool et al. (nor the secondary references) to use "a hyperthermophilic alpha-galactosidase from *T. maritima* to hydrolyze galactose-containing oligosaccharides in a solid substrate intended for animal feed in a method comprising steam heating."

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While it is not argued that improper hindsight is impermissible, it is noted that the motivation to combine, as well as the expectation of success, may come not only from the prior art, but also from the general state of the art at the time the invention was made. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

To the point of the rejection, the Examiner indeed provided sound logic and basis for motivation to combine the references, stemming from the references themselves. As previously stated on the record, Yernool et al. disclose the advantages of using hyperthermophilic alpha-galactosidases to hydrolyze oligosaccharides to galactose, under extreme heat conditions which would otherwise denature heat-labile enzymes. The use of such alpha-Gal enzymes for the improved heat-stable hydrolysis of oligosaccharides, in the production of animal feeds, soy products, and "human foods", were all disclosed and suggested by the references, as provided above. "The thermostable enzyme is used in high-temperature processing of soy products to remove alpha-galactosides" (Yernool abstract; col. 1-2), acting upon raffinose and stachyose to hydrolyze them to their constituent sugars, including galactose (Yernool, col. 11, 16). "The *Thermotoga* alpha-galactosidase of the invention can be used for any purpose for which alpha-galactosidase is used" (col. 10). For example, soy meal can be heat-treated, along with the addition of the thermostable alpha-galactosidase "to produce feeds that can be fed to non-ruminants, such as chicken and pigs." "The use of the alpha-galactosidase in this step further improves the digestibility and nutritional quality of the feed. Both normal and de-fatted soy products may be utilized (bottom, col. 10). The alpha-gal. enzyme may also be used "in any heated, cooked or baked product in which soy meal or defatted soy flour is presently used", as well as with soy milk and soy yogurt (col. 10-11). Another use for the thermostable alpha-galactosidase is in the hydrolysis of raffinose in sugar beets, into its constituent sugars of galactose and sucrose (col. 11). While the enzyme was stated to be used "between about 84° C and 100° C" for the hydrolysis of flatulence-causing oligosaccharides, it had a temperature optimum of 93° C (col. 16).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "steam heating" and "solid

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substrate") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). While new claim 58 does recite the step of "steam heating", it was previously noted that Yernool et al. disclosed that the thermostable alpha-Gal enzyme from *Thermotoga neapolitana* has activity up to and including 100° C (col. 3), and further, "generally, the methods comprise heating the soy products to a temperature at least as high as about 65-70° C (preferably 70-105° C...)." Thus and again, one of ordinary skill in the art would readily have expected, and been motivated, to utilize the enzyme within the instantly-claimed ranges between 80° C and 100° C. Performance of the methods of the reference in a temperature range of 70-105° C, as disclosed therein, would naturally have produced and utilized steam, since the boiling point of water is 100° C.

Regarding the use of solid substrates (claim 58), it was previously noted that Yernool et al. taught that "the *Thermotoga* alpha-galactosidase of the invention can be used for any purpose for which alpha-galactosidase is used" (col. 10). For example, soy meal can be heat-treated, along with the addition of the thermostable alpha-galactosidase "to produce feeds that can be fed to non-ruminants, such as chicken and pigs." "The use of the alpha-galactosidase in this step further improves the digestibility and nutritional quality of the feed. Both normal and de-fatted soy products may be utilized (bottom, col. 10). The alpha-gal. enzyme may also be used "in any heated, cooked or baked product in which soy meal or defatted soy flour is presently used" (col. 10-11). Another use for the thermostable alpha-galactosidase is in the hydrolysis of raffinose in sugar beets, into its constituent sugars of galactose and sucrose (col. 11).

### ***Conclusion***

Applicant's amendment (adding claim 58) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



KEITH HENDRICKS  
PRIMARY EXAMINER